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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE SELENIOUS ACID LITIGATION	Honorable Brian R. Martinotti, U.S.D.J. Civil Action No. 24 CV 7791(BRM)(CLW) (consolidated) **DEFENDANTS, SOMERSET THERAPEUTICS, LLC, SOMERSET PHARMA, LLC, AND ODIN PHARMACEUTICALS, LLC'S ANSWER, SEPARATE DEFENSES, JURY DEMAND AND COUNTERCLAIMS TO COMPLAINT FOR PATENT INFRINGEMENT (ORIGINALLY FILED IN 24 CV 11138)**

Defendants Somerset Therapeutics, LLC, Somerset Pharma, LLC, and Odin Pharmaceuticals, LLC (collectively "Somerset" or "Defendant"), by and through its undersigned counsel, provide the following answer, separate defenses, and counterclaims to the Complaint for Patent Infringement ("Complaint") (D.I. 1 originally filed in 24 CV 11138) of Plaintiff American Regent, Inc. ("ARI" or "Plaintiff"). This pleading is based upon Somerset's knowledge as to its own activities, and upon information and belief as to other matters. Pursuant to Fed. R. Civ. P.

8(b)(3), Somerset denies all allegations in Plaintiff's Complaint except those admitted specifically below.

NATURE OF THIS ACTION

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 et. seq., arising from Somerset's submission to the United States Food and Drug Administration ("FDA") of Abbreviated New Drug Application No. 218780 ("the ANDA") which contains a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("Paragraph IV Certification") seeking approval to engage in the commercial manufacture, use, sale, and/or importation a generic version of ARI's Selenious Acid products ("the ANDA Product") prior to the expiration of United vStates Patent No. 11,998,565 ("the '565 patent") and 12,150,957 ("the '957 patent") (collectively, the "Asserted Patents"). As discussed below, this case involves the same ANDA No. 218780 and thus is a related case to *American Regent, Inc. v. Somerset Therapeutics, LLC*, C.A. No. 24-7807 (D.N.J.).

ANSWER: Somerset admits that Somerset Therapeutics, LLC submitted ANDA No. 218780 ("Somerset's ANDA") to the FDA seeking approval to commercially market a generic version of selenious acid injection ("Somerset's Proposed Product") prior to the expiration of the '565 and '957 patents. Somerset further admits that Plaintiff's Complaint purports to bring an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, but denies that Plaintiff is entitled to any relief. Somerset denies the remaining allegations this paragraph.

THE PARTIES

2. ARI is a corporation organized and existing under the laws of the State of New York, with a principal place of business at 5 Ramsey Road, Shirley, New York 11967.

ANSWER: Somerset lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of this paragraph, and therefore denies the same.

3. On information and belief, Somerset Therapeutics, LLC is a limited liability corporation organized under the laws of the State of Delaware, having a principle place of business at 6100 Hollywood Blvd., Hollywood, Florida, and an established and regular place of business at 300 Franklin Square Drive, Somerset, New Jersey.

ANSWER: Somerset admits Somerset Therapeutics, LLC is a limited liability company

organized and existing under the laws of Delaware, having a place of business at 300 Franklin Square Drive, Somerset, New Jersey. Somerset denies the remaining allegations of this paragraph.

4. On information and belief, Somerset Pharma, LLC is a limited liability corporation organized under the laws of the State of Delaware, having a principle place of business at 300 Franklin Square Drive, Somerset, New Jersey.

ANSWER: Somerset admits Somerset Pharma, LLC is a limited liability company organized and existing under the laws of Delaware, having a place of business at 300 Franklin Square Drive, Somerset, New Jersey 08873. Somerset denies the remaining allegations of this paragraph.

5. On information and belief, Somerset Therapeutics, LLC is privately owned pharmaceutical company that manufactures and holds the intellectual property rights and marketing authorizations for generic injectable and ophthalmic drugs.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset admits that it markets and sells generic pharmaceutical products throughout the United States. Somerset denies the remaining allegations of this paragraph.

6. On information and belief, Somerset Pharma, LLC is a wholly-owned subsidiary of Somerset Therapeutics, LLC.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset admits that Somerset Pharma, LLC is a wholly owned subsidiary of Somerset Therapeutics, LLC.

7. On information and belief, Defendant Odin Pharmaceuticals, LLC, is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 300 Franklin Square Drive, Somerset, New Jersey 08873-4187.

ANSWER: Somerset admits Odin Pharmaceuticals, LLC is a limited liability company organized and existing under the laws of Delaware, having a place of business at 300 Franklin Square Drive, Somerset, New Jersey 08873. Somerset denies the remaining allegations of this

paragraph.

8. On information and belief, Somerset Therapeutics, LLC, Somerset Pharma, LLC, and Odin Pharmaceuticals, LLC, acted in concert to prepare and submit the ANDA to the FDA.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset admits that Somerset Therapeutics, LLC submitted ANDA No. 218780 to the FDA. Somerset denies the remaining allegations of this paragraph.

JURISDICTION AND VENUE

9. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 *et. seq.*, and jurisdiction is proper under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset does not contest jurisdiction for the purposes of this action only, and expressly reserves the right to contest jurisdiction in any other case as to any party. Somerset otherwise denies the remaining allegations of Paragraph 9.

10. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b), at least because, on information and belief, Somerset submitted the ANDA from their Somerset, New Jersey place of business and therefore Somerset has committed acts of infringement and have a regular and established place of business in New Jersey for the purposes of venue.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset does not contest venue for the purposes of this action only, and expressly reserves the right to contest venue in any other case as to any party. Somerset otherwise denies the remaining allegations of Paragraph 10.

11. Based on the facts and causes alleged herein, including infringement under 35 U.S.C. § 271(e)(2) by the ANDA and for additional reasons to be further developed through discovery if necessary, this Court has personal jurisdiction over Somerset.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other

case as to any party. Somerset otherwise denies the remaining allegations of Paragraph 11.

12. On information and belief, Somerset Pharma, LLC has its principal places of business in the State of New Jersey and has registered to do business with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0450400310. Somerset Pharma, LLC has thus consented to personal jurisdiction in New Jersey.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Somerset admits Somerset Pharma, LLC is registered to do business with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0450400310. Somerset otherwise denies the remaining allegations of Paragraph 12.

13. On information and belief, Somerset Pharma, LLC and Somerset Therapeutics, LLC are affiliates that operate within the same corporate family.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset admits that Somerset Pharma, LLC is a subsidiary of Somerset Therapeutics, LLC. Somerset otherwise denies the remaining allegations of Paragraph 13.

14. On information and belief, Somerset Therapeutics, LLC has registered to do business with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0451084958. Somerset Pharma, LLC has thus consented to personal jurisdiction in New Jersey.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Somerset admits Somerset Therapeutics, LLC is registered to do business with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating

in New Jersey under Business ID No. 0451084958. Somerset otherwise denies the remaining allegations of Paragraph 14.

15. On information and belief, Somerset Therapeutics, LLC and Somerset Pharma, LLC act, operate, and/or hold themselves out to the public as a single integrated business such that Somerset Therapeutics, LLC has an established and regular place of business in the State of New Jersey at least through activities performed in conjunction with Somerset Pharma, LLC.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Somerset otherwise denies the allegations of Paragraph 15.

16. On information and belief, Odin Pharmaceuticals, LLC has its principal places of business in the State of New Jersey and has registered to do business with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0450315269. Odin Pharmaceuticals, LLC has thus consented to personal jurisdiction in New Jersey.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Somerset admits Odin Pharmaceuticals, LLC is registered to do business with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0450315269. Somerset otherwise denies the remaining allegations of Paragraph 16.

17. On information and belief, Somerset Therapeutics, LLC, with the aid of Somerset Pharma, LLC and Odin Pharmaceuticals, LLC, filed the ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the generic product described in the ANDA in the United States, including in New Jersey.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other

case as to any party. Somerset further admits that Somerset Therapeutics, LLC submitted ANDA No. 218780 to FDA. Somerset otherwise denies the remaining allegations of Paragraph 17.

18. On information and belief, actions related to the submission of the ANDA occurred in the State of New Jersey, and if Somerset receives approval for the ANDA, Somerset will market, distribute, offer for sale, and/or sell the generic product described in the ANDA in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of the generic product described in the ANDA in the State of New Jersey. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 763 (Fed. Cir. 2016).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Somerset otherwise denies the remaining allegations of Paragraph 18.

19. On information and belief, if the ANDA is approved, the generic product described in the ANDA would, among other things, be manufactured, marketed, distributed, offered for sale, and/or sold in New Jersey, prescribed by physicians practicing in New Jersey, dispensed by pharmacies located within New Jersey, and/or used by patients in New Jersey, all of which would have a substantial effect on New Jersey.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Somerset otherwise denies the remaining allegations of Paragraph 19.

20. On information and belief, and as confirmed by Somerset Pharma, LLC's website, Somerset Pharma, LLC, Somerset Therapeutics, LLC, and Odin Pharmaceuticals, LLC operate publicly as "Team Somerset Pharma," wherein the Somerset Therapeutics, LLC name is placed on product labels, Somerset Pharma, LLC is the entity that develops and commercializes the products in the US, and Odin Pharmaceuticals, LLC "operates as a research and development facility that supports all R&D efforts undertaken by Somerset Pharma."

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Somerset otherwise denies the remaining allegations of Paragraph 20.

21. On information and belief, Somerset Therapeutics, LLC, Somerset Pharma, LLC, and Odin Pharmaceuticals, LLC operate under common management by Key Managerial Persons ("KMP"). Somerset Therapeutics, LLC, Somerset Pharma, LLC, and Odin Pharmaceuticals, LLC are all "Enterprise[s] over which KMP have significant influence."

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Somerset otherwise denies the remaining allegations of Paragraph 21.

22. On information and belief, following any FDA approval of the ANDA, Somerset Therapeutics, LLC, Somerset Pharma, LLC, and Odin Pharmaceuticals, LLC will work in concert with one another to make, use, offer to sell, and/or sell the ANDA Product throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Somerset otherwise denies the remaining allegations of Paragraph 22.

23. On information and belief, Somerset derives substantial revenue from the marketing, manufacture, and/or sale of generic pharmaceutical products in the United States and New Jersey.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Somerset otherwise denies the remaining allegations of Paragraph 23.

24. On information and belief, Somerset Pharma, LLC and Somerset Therapeutics, LLC have previously been sued in this District and have not challenged personal jurisdiction or venue. *See, Nexus Pharms., Inc. v. Somerset Pharma, LLC et al.*, Civil Action No. 23-1248 (ZNQ) (RLS) (D.N.J.).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset admits that Somerset was a party to the lawsuit

identified in Paragraph 24. Somerset does not contest personal jurisdiction for the purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party. Somerset otherwise denies the remaining allegations of Paragraph 24.

BACKGROUND

25. ARI holds New Drug Application ("NDA") No. 209379 for Selenious Acid ((1) eq. 600 mcg Selenium/10 mL (eq. 60 mcg Selenium/mL), (2) eq. 60 mcg Selenium/mL (eq. 60 mcg Selenium/mL), and (3) eq. 12 mcg Selenium/2 mL (eq. 6 mcg Selenium/mL)), which was originally approved by the FDA on April 30, 2019, which ARI manufactures and sells in this Judicial District and throughout the United States.

ANSWER: Somerset admits that the FDA's website indicates that ARI is the holder of New Drug Application ("NDA") No. 209379 for Selenious Acid ((1) eq. 600 mcg Selenium/10 mL (eq. 60 mcg Selenium/mL) (2) eq. 60 mcg Selenium/mL (eq. 60 mcg Selenium/mL), and (3) eq. 12 mcg Selenium/2 mL (eq. 6 mcg Selenium/mL)). Somerset lacks information or knowledge sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph, and therefore denies the same.

26. ARI's Selenious Acid products or the use of ARI's Selenious Acid products are covered by one or more claims of the Asserted Patents.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset lacks information or knowledge sufficient to form a belief as to the truth or falsity of the allegations of this paragraph, and therefore denies the same.

27. ARI is the owner of the '565 patent, which is entitled "Trace element compositions, methods of making and use" and was duly and legally issued on June 4, 2024. A copy of the '565 patent is attached as Exhibit A.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset admits that on its face, the '565 patent was issued on June 4, 2024, and is entitled "Trace Element Compositions, Methods of Making and Use." Somerset admits that a purported copy of the '565 patent is attached to the Complaint as Exhibit

A. Somerset specifically denies that the ’565 patent was duly and lawfully issued. Somerset denies the remaining allegations of this paragraph.

28. The ’565 patent has been listed in connection with ARI’s Selenious Acid products in the FDA’s publication Approved Drug Products with Therapeutic Equivalence Evaluations (the “Orange Book”).

ANSWER: Somerset admits that the ’565 patent is listed in the FDA’s Orange Book in connection with Selenious Acid products. Somerset denies the remaining allegations of this paragraph.

29. As indicated in the Orange Book, the patent expiration date for the '565 patent is July 1, 2041.

ANSWER: Somerset admits that the ’565 patent is listed in the Orange Book with an expiration date of July 1, 2041. Somerset denies the remaining allegations of this paragraph.

30. On information and belief, Somerset was responsible for preparing the ANDA which contained a Paragraph IV Certification.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset admits that Somerset Therapeutics, LLC filed ANDA No. 218780 seeking approval to engage in the commercial manufacture, use, or sale of Somerset’s Proposed Product. Somerset otherwise denies the remaining allegations of Paragraph 30.

31. By letter dated June 10, 2024 (“the First Notice Letter”), Somerset notified ARI that, pursuant to the Federal Food, Drug, and Cosmetic Act, Somerset had submitted the ANDA with a Paragraph IV Certification to the FDA to seek approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of a generic version of ARI’s Selenious Acid product (eq. 600 mcg Selenium/10 mL (eq. 60 mcg Selenium/mL)) (“the Original ANDA Product”), prior to the expiration of the ’565 patent.

ANSWER: Somerset admits that on June 11, 2024, Somerset Therapeutics, LLC sent Somerset’s First Notice Letter. Somerset further admits that Somerset’s Notice informed Plaintiff that Somerset filed ANDA No. 218780 seeking approval to engage in the commercial manufacture, use, or sale of Somerset’s Proposed Product before the expiration of the ’565 patent. Somerset

denies the remaining allegations of Paragraph 31.

32. On July 16, 2024, ARI subsequently sued Somerset regarding the ANDA and the Original ANDA product. *See American Regent, Inc. v. Somerset Therapeutics, LLC*, C.A. No. 24-7807, ECF No. 1 (D.N.J. July 16, 2024).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset admits that Somerset is a party to the lawsuit identified in Paragraph 32. Somerset denies the remaining allegations of Paragraph 32.

33. By letter dated November 20, 2024 ("the Second Notice Letter"), Somerset notified ARI that Somerset had filed an amendment to the ANDA ("the Amended ANDA") to additionally seek approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of a generic version of ARI's Selenious Acid product (eq. 12 mcg Selenium/2 mL (eq. 6 mcg Selenium/mL)) ("the Amended ANDA Product"), prior to the expiration of the '565 patent.

ANSWER: Somerset admits that on November 19, 2024, Somerset Therapeutics, LLC sent Somerset's Second Notice Letter. Somerset further admits that Somerset's Notice informed Plaintiff that Somerset filed ANDA No. 218780 seeking approval to engage in the commercial manufacture, use, or sale of Somerset's Proposed Product before the expiration of the '565 patent. Somerset denies the remaining allegations of Paragraph 33.

34. On information and belief, Somerset submitted the ANDA to the FDA, which contained a Paragraph IV Certification asserting that the '565 patent will not be infringed by the manufacture, use, offer for sale, sale, or importation of the ANDA Product, or alternatively, that the '565 patent is invalid.

ANSWER: Somerset admits that Somerset Therapeutics, LLC submitted ANDA No. 218780 to FDA. Somerset further admits that ANDA No. 218780 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the claims of the '565 patent are invalid, unenforceable, and/or will not be infringed by the activities described in Somerset's ANDA. Somerset denies the remaining allegations of Paragraph 32.

35. The Second Notice Letter contained no non-infringement defenses for claims 1, 2-10, 12-19, 21-25, and 27-29 of the '565 patent.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To

the extent a response is required, Somerset admits that Somerset's Second Notice Letter contains non-infringement positions for certain claims the '565 Patent. Somerset otherwise denies the allegations of this paragraph.

36. Since ARI received the Second Notice Letter, the '957 patent has been listed in connection with ARI's Selenious Acid products in the Orange Book.

ANSWER: Somerset admits that the '957 patent is listed in the FDA's Orange Book in connection with Selenious Acid products. Somerset denies the remaining allegations of this paragraph.

37. ARI is the owner of the '957 patent, entitled "Trace element compositions, methods of making and use," which was duly and legally issued on November 26, 2024. A copy of the '957 patent is attached as Exhibit B.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset admits that on its face, the '957 patent was issued on November 26, 2024, and is entitled "Trace Element Compositions, Methods of Making and Use." Somerset admits that a purported copy of the '957 patent is attached to the Complaint as Exhibit B. Somerset specifically denies that the '957 patent was duly and lawfully issued. Somerset denies the remaining allegations of this paragraph.

38. As indicated in the Orange Book, the patent expiration date for the '957 patent is July 1, 2041.

ANSWER: Somerset admits that the '957 patent is listed in the Orange Book with an expiration date of July 1, 2041. Somerset denies the remaining allegations of this paragraph.

39. On information and belief, as indicated in the Second Notice Letter, the Amended ANDA Product is a generic version of ARI's Selenious Acid product (eq. 12 mcg Selenium/2 Ml (eq. 6 mcg Selenium/mL)), as its reference listed drug, containing the same or equivalent ingredients in the same or equivalent amounts.

ANSWER: Somerset admits that Somerset Therapeutics, LLC submitted ANDA No. 218780 to the FDA seeking approval to commercially market a generic version of Selenious Acid

products. Somerset otherwise denies the allegations of this paragraph.

40. In the Second Notice Letter, Somerset disclosed that the Amended ANDA Product is Selenious Acid Injection, USP, (12 mcg Selenium/2 mL (6 mcg Selenium/mL)).

ANSWER: Somerset admits that Somerset Therapeutics, LLC submitted ANDA No. 218780 to the FDA seeking approval to commercially market a generic version of Selenious Acid products. Somerset otherwise denies the allegations of this paragraph.

41. On information and belief, the Amended ANDA Product contains the same or equivalent ingredients in the same or equivalent amounts as ARI's Selenious Acid products (eq. 12 mcg Selenium/2 mL (eq. 6 mcg Selenium/mL)).

ANSWER: Somerset admits that Somerset Therapeutics, LLC submitted ANDA No. 218780 to the FDA seeking approval to commercially market a generic version of Selenious Acid products. Somerset otherwise denies the allegations of this paragraph.

42. On information and belief, the Amended ANDA Product will feature the same or equivalent chemical and therapeutic properties as ARI's Selenious Acid products.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset lacks information or knowledge sufficient to form a belief as to the truth or falsity of the allegations of this paragraph, and therefore denies the same.

COUNT I: INFRINGEMENT OF THE '565 PATENT

43. ARI realleges paragraphs 1-42 as if fully set forth herein.

ANSWER: To the extent an answer to Paragraph 43 is required, Somerset incorporates by reference its answers to the foregoing paragraphs as if fully set forth herein.

44. Somerset's submission of the ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of the ANDA Product in or into the United States, prior to the expiration of the '565 patent, constitutes direct and indirect infringement of the '565 patent pursuant to 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset denies the allegations of Paragraph 44.

45. On information and belief, the ANDA Product, if approved by FDA, will be manufactured, used, offered for sale, sold, and/or imported in or into the United States by Somerset or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of one or more claims of the '565 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. On information and belief, the administration of the ANDA Product will occur with Somerset's specific intent and encouragement, and will be conduct that Somerset knows or should know will occur. On information and belief, Somerset will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of ARI's rights under the '565 patent.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset denies the allegations of Paragraph 45.

46. On information and belief, Somerset's manufacturing, use, offer for sale, sale, and/or importation of the ANDA Product, once the ANDA is approved by FDA, would constitute direct infringement under 35 U.S.C. § 271(a), induced infringement under 35 U.S.C. § 271(b), and contributory infringement under 35 U.S.C. § 271(c) of one or more claims of the '565 patent, either literally or under the doctrine of equivalents. On information and belief, Somerset intends that the ANDA Product be used by patients and medical professionals. Also, on information and belief, Somerset knows that the ANDA Product is especially made or adapted for use in infringing the '565 patent, and that the ANDA Product is not suitable for substantial non-infringing use.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset denies the allegations of Paragraph 46.

47. ARI will be irreparably harmed if Somerset is permitted to make, use, sell, offer to sell, and/or import the ANDA Product in or into the United States, and is not enjoined from doing so. ARI is entitled to relief provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of the ANDA be a date that is not earlier than the expiration date of the '565 patent, or any later expiration of exclusivity for the '565 patent to which ARI is or becomes entitled, and an injunction against such infringement. ARI does not have an adequate remedy at law.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset denies the allegations of Paragraph 47.

48. Somerset has had knowledge of the '565 patent since at least the date Somerset submitted the ANDA with a Paragraph IV Certification and was aware that submission of the ANDA with a Paragraph IV Certification constituted an act of infringement under 35 U.S.C. § 271(e)(2).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To

the extent a response is required, Somerset denies the allegations of Paragraph 48.

49. This case is "exceptional," and ARI is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset denies the allegations of Paragraph 49.

COUNT II: INFRINGEMENT OF THE '957 PATENT

50. ARI realleges paragraphs 1-49 as if fully set forth herein.

ANSWER: To the extent an answer to Paragraph 50 is required, Somerset incorporates by reference its answers to the foregoing paragraphs as if fully set forth herein.

51. Somerset's submission of the ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of the ANDA Product in or into the United States, prior to the expiration of the '957 patent, constitutes direct and indirect infringement of the '957 patent pursuant to 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset denies the allegations of Paragraph 51.

52. On information and belief, the ANDA Product, if approved by FDA, will be manufactured, used, offered for sale, sold, and/or imported in or into the United States by Somerset or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of one or more claims of the '957 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. On information and belief, the administration of the ANDA Product will occur with Somerset's specific intent and encouragement, and will be conduct that Somerset knows or should know will occur. On information and belief, Somerset will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of ARI's rights under the '957 patent.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset denies the allegations of Paragraph 52.

53. On information and belief, Somerset's manufacturing, use, offer for sale, sale, and/or importation of the ANDA Product, once the ANDA is approved by FDA, would constitute direct infringement under 35 U.S.C. § 271(a), induced infringement under 35 U.S.C. § 271(b), and contributory infringement under 35 U.S.C. § 271(c) of one or more claims of the '957 patent, either

literally or under the doctrine of equivalents. On information and belief, Somerset intends that the ANDA Product be used by patients and medical professionals. Also, on information and belief, Somerset knows that the ANDA Product is especially made or adapted for use in infringing the '957 patent, and that the ANDA Product is not suitable for substantial non-infringing use.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset denies the allegations of Paragraph 53.

54. ARI will be irreparably harmed if Somerset is permitted to make, use, sell, offer to sell, and/or import the ANDA Product in or into the United States, and is not enjoined from doing so. ARI is entitled to relief provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of the ANDA be a date that is not earlier than the expiration date of the '957 patent, or any later expiration of exclusivity for the '957 patent to which ARI is or becomes entitled, and an injunction against such infringement. ARI does not have an adequate remedy at law.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset denies the allegations of Paragraph 54.

55. Somerset has had knowledge of the '957 patent since at least the date Somerset submitted the ANDA with a Paragraph IV Certification and was aware that submission of the ANDA with a Paragraph IV Certification constituted an act of infringement under 35 U.S.C. § 271(e)(2).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset denies the allegations of Paragraph 55.

56. This case is "exceptional," and ARI is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent a response is required, Somerset denies the allegations of Paragraph 56.

PRAYER FOR RELIEF

The remainder of Plaintiff's Complaint recites a prayer for relief for which no response is required. To the extent a response is required, Somerset denies that Plaintiff is entitled to any remedy or relief.

JURY DEMAND

Plaintiff's demand for a jury trial requires no response. Somerset demands a jury trial of all issues so triable.

SEPARATE DEFENSES

Somerset asserts the following defenses without prejudice to the denials in this Answer, and without admitting any allegations of the Complaint not otherwise admitted. Somerset does not assume the burden of proof on any such defenses, except as required by applicable law with respect to the particular defense asserted. Somerset reserves the right to assert other defenses and/or to otherwise supplement this Answer upon discovery of facts or evidence rendering such action appropriate.

FIRST DEFENSE

Each purported claim in the Complaint, in whole or in part, is barred for failure to state a claim upon which relief can be granted.

SECOND DEFENSE

The claims of the '565 and '957 patents are invalid for failure to comply with the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially created bases for invalidity.

THIRD DEFENSE

Somerset does not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '565 and '957 patents. If the products that are the subject of ANDA No. 218780 were marketed, Somerset would not infringe any valid and enforceable claim of the '565 patent.

FOURTH DEFENSE

Somerset has not, does not, and will not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the '565 and '957 patents. If the products that are the subject of ANDA No. 218780 were marketed, Somerset would not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the '565 and '957 patents.

FIFTH DEFENSE

The claims of the '565 and '957 patents are barred in whole or in part by the doctrine of prosecution history estoppel, judicial estoppel, and/or other equitable doctrines.

SIXTH DEFENSE

Somerset's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

SEVENTH DEFENSE

Any additional defenses or counterclaims that discovery may reveal.

COUNTERCLAIMS

For its Counterclaims against American Regent, Inc., ("ARI" or "Counterclaim Defendant/Plaintiff"), Counterclaim Plaintiffs/Defendants Somerset Therapeutics, LLC, Somerset Pharma, LLC, and Odin Pharmaceuticals, LLC (together "Somerset" or "Counterclaim Plaintiffs/Defendants"), states as follows:

THE PARTIES

1. On information and belief, American Regent, Inc. is a corporation organized and existing under the laws of the State of New York, with a principal place of business at 5 Ramsey Road, Shirley, New York 11967.

2. On information and belief, Somerset Therapeutics, LLC is a limited liability

corporation organized under the laws of the State of Delaware, having a place of business at 300 Franklin Square Drive, Somerset, New Jersey 08873.

3. On information and belief, Somerset Pharma, LLC is a limited liability corporation organized under the laws of the State of Delaware, having a place of business at 300 Franklin Square Drive, Somerset, New Jersey 08873.

4. On information and belief, Defendant Odin Pharmaceuticals, LLC, is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 300 Franklin Square Drive, Somerset, New Jersey 08873.

JURISDICTION AND VENUE

5. These counterclaims arise under the patent laws of the United States and the Declaratory Judgment Act. This Court has subject matter jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

6. This Court has personal jurisdiction over Counterclaim Defendant/Plaintiff on the basis of, *inter alia*, their contacts with New Jersey relating to the subject matter of this action, including having filed suit.

7. Venue is proper under 28 U.S.C. §§ 1391 and 1400.

BACKGROUND

8. On information and belief, ARI holds approved New Drug Application ("NDA") No. 209379 for Selenious Acid brand trace element injection.

9. An NDA must include, among other things, the number of any patent that claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an authorized party. *See* 21 U.S.C. § 355(b)(1), (c)(2); 21 C.F.R. § 314.53(b), (c)(2).

10. Upon approval of the NDA, the U.S. Food and Drug Administration ("FDA") publishes patent information for the approved drug in the "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." *See* 21 U.S.C. § 355(j)(7)(A)(iii).

11. U.S. Patent 11,998,565 ("the '565 patent"), titled "Trace Element Compositions, Methods of Making and Use," issued on June 4, 2024.

12. U.S. Patent 12,150,957 ("the '957 patent"), titled "Trace Element Compositions, Methods of Making and Use," issued on November 26, 2024.

13. On information and belief, American Regent, Inc. is the assignee of the '565 and '957 patents.

14. Upon information and belief, Counterclaim Defendant/Plaintiff caused the '565 and '957 patents to be listed in the Orange Book as a patent that claims such a drug for which ARI submitted NDA No. 209379.

15. Somerset Therapeutics, LLC submitted Abbreviated New Drug Application ("ANDA") No. 218780 ("Somerset ANDA") to obtain FDA approval to market a generic version of Selenious Acid products ("Somerset's ANDA Product") prior to the expiration of the '565 and '957 patents.

16. By letter dated June 11, 2024 (the "Somerset First Notice Letter"), pursuant to 21 U.S.C. § 355(j)(2)(B), Somerset Therapeutics, LLC notified Counterclaim Defendant/Plaintiff that ANDA No. 218780 includes a Paragraph IV Certification with respect to the '565 patent. The Somerset First Notice Letter, which is incorporated herein by reference, contained a detailed statement of the factual and legal bases for Somerset Paragraph IV Certification that the claims of the '565 patent are invalid, not infringed, and/or unenforceable.

17. By letter dated November 19, 2024 (the "Somerset Second Notice Letter"), pursuant to 21 U.S.C. § 355(j)(2)(B), Somerset Therapeutics, LLC notified Counterclaim Defendant/Plaintiff that ANDA No. 218780 includes a Paragraph IV Certification with respect to the '565 patent. The Somerset Second Notice Letter, which is incorporated herein by reference, contained a detailed statement of the factual and legal bases for Somerset Paragraph IV Certification that the claims of the '565 patent are invalid, not infringed, and/or unenforceable.

18. By letter dated December 20, 2024 (the "Somerset Third Notice Letter"), pursuant to 21 U.S.C. § 355(j)(2)(B), Somerset Therapeutics, LLC notified Counterclaim Defendant/Plaintiff that ANDA No. 218780 includes a Paragraph IV Certification with respect to the '957 patent. The Somerset Third Notice Letter, which is incorporated herein by reference, contained a detailed statement of the factual and legal bases for Somerset Paragraph IV Certification that the claims of the '957 patent are invalid, not infringed, and/or unenforceable.

19. On December 13, 2024, Counterclaim Defendant/Plaintiff filed this instant lawsuit alleging infringement of the '565 and '957 patents.

COUNT I
(Declaratory Judgment of Non-Infringement of the '565 Patent)

20. Somerset re-alleges and incorporates by reference the allegations in Paragraphs 1 through 16 of its Counterclaims as though fully set forth herein.

21. Counterclaim Defendant/Plaintiff allege ownership of the '565 patent and have brought claims against Somerset alleging infringement of the '565 patent.

22. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Somerset's ANDA and/or the commercial marketing of Somerset's ANDA Product infringe, have infringed, and/or will infringe a valid and enforceable claim of the '565 patent.

23. Somerset has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the ’565 patent and is not liable for such infringement.

24. Somerset is entitled to a declaration that the manufacture, use, or sale of Somerset’s ANDA Product would not infringe any valid or enforceable claim of the ’565 patent.

COUNT II
(Declaratory Judgment of Invalidity or Unenforceability of the ’565 Patent)

25. Somerset re-alleges and incorporates by reference the allegations in Paragraphs 1 through 21 of its Counterclaims as though fully set forth herein.

26. Counterclaim Defendant/Plaintiff allege ownership of the ’565 patent and have brought claims against Somerset alleging infringement of the ’565 patent.

27. One or more claims of the ’565 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity.

28. The ’565 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

29. The alleged invention of the ’565 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the ’565 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the ’565 patent and would have had a reasonable expectation of success in doing so.

30. The subject matter claimed in the ’565 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are

such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

31. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Somerset's ANDA and/or the commercial marketing of Somerset's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '565 patent.

32. Somerset is entitled to a declaration that all claims of the '565 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity.

COUNT III
(Declaratory Judgment of Non-Infringement of the '957 Patent)

33. Somerset re-alleges and incorporates by reference the allegations in Paragraphs 1 through 31 of its Counterclaims as though fully set forth herein.

34. Counterclaim Defendant/Plaintiff allege ownership of the '957 patent and have brought claims against Somerset alleging infringement of the '957 patent.

35. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Somerset's ANDA and/or the commercial marketing of Somerset's ANDA Product infringe, have infringed, and/or will infringe a valid and enforceable claim of the '957 patent.

36. Somerset has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '957 patent and is not liable for such infringement.

37. Somerset is entitled to a declaration that the manufacture, use, or sale of

Somerset's ANDA Product would not infringe any valid or enforceable claim of the '957 patent.

COUNT II
(Declaratory Judgment of Invalidity or Unenforceability of the '957 Patent)

38. Somerset re-alleges and incorporates by reference the allegations in Paragraphs 1 through 36 of its Counterclaims as though fully set forth herein.

39. Counterclaim Defendant/Plaintiff allege ownership of the '957 patent and have brought claims against Somerset alleging infringement of the '957 patent.

40. One or more claims of the '957 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity.

41. The '957 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

42. The alleged invention of the '957 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '957 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '957 patent and would have had a reasonable expectation of success in doing so.

43. The subject matter claimed in the '957 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

44. There is an actual, substantial, continuing, and justiciable controversy between the

parties regarding whether the filing of Somerset's ANDA and/or the commercial marketing of Somerset's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '957 patent.

45. Somerset is entitled to a declaration that all claims of the '957 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially-created bases for invalidity.

PRAYER FOR RELIEF

WHEREFORE, Somerset respectfully requests judgment in its favor and against Counterclaim Defendant/Plaintiff as follows:

a. Declaring that the filing of Somerset's ANDA No. 218780 has not infringed and does not infringe any valid and enforceable claim of the '565 patent;

b. Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of Somerset's ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the '565 patent;

c. Declaring that the filing of Somerset's ANDA No. 218780 has not infringed and does not infringe any valid and enforceable claim of the '957 patent;

d. Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of Somerset's ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the '957 patent;

e. Declaring this an exceptional case in favor of Somerset and awarding its attorneys' fees pursuant to 35 U.S.C. § 285 and/or under all applicable statutes and rules in common law that would be appropriate;

f. Awarding costs and expenses under all applicable statutes and rules in common

law that would be appropriate; and

g. Awarding any and all such other relief as the Court determines to be just and proper.

MIDLIGE RICHTER LLC
Attorneys for Defendants, Somerset Therapeutics, LLC, Somerset Pharma, LLC and Odin Pharmaceuticals, LLC

By: s/ James S. Richter
James S. Richter
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Dated: January 9, 2025

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LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

s/ James S. Richter
James S. Richter

Dated: January 9, 2025

LOCAL CIVIL RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the parties seek, *inter alia*, declaratory relief in their respective pleadings.

I hereby certify under penalty of perjury that the foregoing is true and correct.

s/ James S. Richter
James S. Richter

Dated: January 9, 2025

CERTIFICATE OF SERVICE

The undersigned attorney certifies that a copy of Somerset's foregoing Answer, Separate Defenses, and Counterclaims was filed via ECF and served on all counsel of record by electronic mail on January 9, 2025.

s/ James S. Richter
James S. Richter

Dated: January 9, 2025